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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/207,649	12/08/1998	SUSAN LINDQUIST	17481-004001	7099

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EXAMINER
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CHERNYSHEV, OLGA N

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/207,649

Applicant(s)

LINDQUIST, SUSAN

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,7-20,22 and 37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 7-20, 22 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Formal matters***

1. Claims 1, 3, 7-20, 22 and 37 are pending in the instant application.  
Claims 1, 3, 7-20, 22 and 37 are under examination in the instant office action.
2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
4. Applicant's arguments filed on October 13, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

### ***Claim Rejections - 35 USC § 103***

5. Claims 1, 3, 7, 9, 12-15, 17-19, 22 and 37 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 for those reasons of record as fully explained in the previous communications of record.

Applicant traverses the rejection on the premises that "Cordell does not describe an assay that uses a yeast host cell expressing a chimeric aggregate-prone amyloid protein comprising a mammalian aggregate-prone amyloid peptide to evaluate candidate substances for their ability to inhibit the aggregation of the aggregate-prone amyloid protein in the yeast cell" (bottom at p. 2 of the Response). Applicant further argues that Patino reference describes yeast protein but does not describe mammalian amyloid protein; Hughes describes monomer interaction but no

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covalent higher-order bait-prey aggregates; Rieger article is limited to interaction between PrP and LRP with no reference to aggregation process; Hitzeman ('622 patent) and Chang ('003 patent) describe secreted proteins and lack disclosure of aggregation of proteins inside the cell (p.3 of the Response). Applicant submits that "[b]ecaues none of the secondary references taken alone or in combination suggests that a yeast cell can be used to screen for a substance that inhibits aggregation of a mammalian aggregate-prone amyloid protein in the yeast cell, these references fail to cure the deficiencies of Cordell". Applicant's arguments have been fully considered but are not persuasive for reasons that follow.

As fully explained in the previous communications of record, the instant inventive concept, such as screening substances that might inhibit aggregation of A $\beta$  or PrP, is fully disclosed in publication of Cordell. If Cordell reference provided examples of using the assay within the yeast cell, the instant reference would be sufficient to establish anticipation under 35 U.S.C. 102. The Examiner maintains that secondary references recited in the text of rejection fully substantiate the obviousness of the instant claimed methods because the deficiencies of Cordell publication as compared to the instant claimed methods are limited to standard procedures or protocols readily known and available to those of ordinary skill in the at the time of the invention. One of ordinary skill in the art at the time of invention would be motivated to use a yeast cell to carry out the assay of Cordell because, first, Cordell document suggests using yeast cells and, second, because yeast cells represent an excellent well-known cellular model to study protein-protein interactions, for example. Thus, in view of the Decision and for reasons of record fully explained in the previous office actions of record, the instant rejection is maintained.

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6. Claims 8, 17-18 and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 further in view of Chalfie et al. for those reasons of record as fully explained in the previous communications of record.

Applicant argues that because Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 do not render the instant invention obvious, reference of Chalfie et al. does not supplement the deficiencies of these references. Applicant's arguments have been fully considered but are not persuasive essentially for reasons of record in section 5 of the instant office action. One of ordinary skill in the art at the time of invention would have found it obvious to use any of the readily available and well known markers/labels to attach to a protein of interest for identification purposes.

7. Claims 7, 10 and 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 further in view of Tikhonenko et al. for those reasons of record as fully explained in the previous communications of record.

Applicant argues that because Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 do not render the instant invention obvious, reference of Tikhonenko et al. does not supplement the deficiencies of these references. Applicant's arguments have been fully considered but are not persuasive essentially for reasons of record in section 5 of the instant office action. One of ordinary skill in the art at the time of invention would have found it obvious to use a glucocorticoid receptor element as a marker protein as explained by Tikhonenko, for example, to compensate the deficiencies of Cordell disclosure.

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8. Claim 16 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 further in view of Nordstedt et al. for those reasons of record as fully explained in the previous communications of record.

Applicant argues that because Cordell et al., Patino et al., Hughes et al., Rieger et al., US Patent 4,775,622 and US Patent 5,010,003 do not render the instant invention obvious, reference of Nordstedt et al. does not supplement the deficiencies of these references. Applicant's arguments have been fully considered but are not persuasive essentially for reasons of record in section 5 of the instant office action. One of ordinary skill in the art at the time of invention would have found obvious to use detection of aggregation by increase protease resistance as taught by Nordstedt.

### ***Conclusion***

9. For reasons entirely explained in the previous communications of record, reasons above and in view of the BPAI Decision of February 27, 2004, the instant rejections are maintained. No claim is allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Olga N. Chernyshev, Ph.D.  
Primary Examiner  
Art Unit 1649

December 4, 2006